Massachusetts Department of Public Health
Division of Epidemiology and Immunization

ALERT

Guillain-Barré Syndrome and Meningococcal Conjugate Vaccine

Updated Information and Recommendations for Vaccination and Reporting

October 7, 2005

On September 30, 2005, the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) issued an alert in response to 5 reports of Guillain-Barré syndrome in adolescents (17-18 years of age) in 4 states (NY, OH, PA, NJ). Neurologic symptoms began within 2-4 weeks of administration of Meningococcal Conjugate Vaccine A, C, Y, and W135 (MCV4), trade name Menactra™, manufactured by sanofi pasteur. On October 6, 2005, CDC published additional information and recommendations regarding vaccination and reporting (MMWR Dispatch Vol.54/October 6, 2005), available at http://www.cdc.gov/mmwr/pdf/wk/mm54d1006.pdf and attached.

More than 2.5 million doses of Menactra have been distributed since licensure in January 2005. The background annual incidence of Guillain-Barré syndrome is estimated at 1-2 cases per 100,000 person-years. Therefore, the rate of Guillain-Barré syndrome, based on the number of cases reported within 6 weeks of administration of Menactra, is similar to what might have been expected to occur by coincidence.

Prelicensure studies did not identify any cases of Guillain-Barré syndrome among 7,000 vaccine recipients. In post licensure studies, conducted by CDC, no cases have been identified among 110,000 recipients in the Vaccine Safety Datalink (VSD) project and other healthcare databases. No increase in Guillain-Barré syndrome was identified in association with a similar vaccine (only containing serogroup C) in the United Kingdom.

Recommendations for Vaccination with Meningococcal Conjugate Vaccine

To date, the evidence is insufficient to conclude that MCV4 causes Guillain-Barré syndrome. An ongoing known risk for serious meningococcal disease exists. Therefore, the CDC is recommending continuation of current vaccination strategies. Whether receipt of MCV4 vaccine might increase the risk for recurrence of Guillain-Barré syndrome is unknown**;** avoiding vaccinating persons who are not at high risk for meningococcal disease and who are known to have experienced Guillain-Barré syndrome previously is prudent.

An updated Vaccine Information Statement (VIS) for meningococcal vaccines (dated 10/7/05) reflects the new recommendations for persons with a history of Guillain-Barré syndrome. This statement is available at http://www.cdc.gov/nip/publications/VIS/default.htm and is attached.

Reporting of Cases of Guillain-Barré Syndrome

CDC is requesting enhanced surveillance for Guillain-Barré syndrome in adolescents 11-19 years of age.

1) **Vaccine Adverse Event Reporting System (VAERS).** FDA and CDC are asking providers and other persons with knowledge of any possible cases of Guillain-Barré syndrome occurring after vaccination with Menactra to report them immediately to the Vaccine Adverse Event Reporting System (VAERS), on the web at www.vaers.hhs.gov or by phone at 1-800-822-7967.
2) **State Health Departments.** CDC further requests that healthcare providers report cases all cases of Guillain-Barré syndrome that occur among persons aged 11-19 years to their *state health department,* regardless of vaccination status. Guillain-Barré syndrome is a reportable condition in Massachusetts (105 CMR 300.00). Providers should report cases of Guillain-Barré syndrome occurring since January 1, 2005, to the Massachusetts Department of Public Health by phone at 617-983-6800 or toll free 888-658-2850, or by fax at 617-983-6813.

Please forward this alert to all pertinent colleagues and staff.